

**REMARKS**

Claims 1 - 35 and 47 - 52 are pending in the present application. In view of the following remarks, it is respectfully submitted that all of the presently pending claims are allowable.

Claims 1 - 4, 6, 9, 10, 12-19, 21, 23, 27, 28, 30 - 35 and 47 - 55 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Published Appln. No. 2005/0038371 to Reich et al. ("Reich") in view of U.S. Patent No. 6,622,036 to Suffin ("Suffin").

Claim 1 recites a method of treating a central nervous system (CNS) disorder, comprising the steps of "inserting into a patient's body first and second conduits so that distal ends of the first and second conduits open to a portion of the patient's CNS with direct access to cerebrospinal fluid (CSF) and so that a proximal end of the first conduit opens into a first reservoir of material to be introduced into the CSF and a proximal end of the second conduit opens to drain CSF withdrawn from the CNS and permanently prevent the withdrawn CSF from reentering the CNS" in combination with "*detecting and analyzing brain activity of a patient*" and "*determining a chemical imbalance present in the CSF based on the detected and analyzed brain activity*" and "treating the patient based on the determined chemical imbalance by one of supplying an agent to the CSF via the first conduit and withdrawing a quantity of CSF via the second conduit."

Initially, it is respectfully submitted that Reich fails to teach or suggest a method comprising "detecting and analyzing brain activity of a patient" and "determining a chemical imbalance present in the CSF based on the detected and analyzed brain activity," as recited in claim 1. Rather, Reich makes no disclosure of a detection of brain activity at all. The Examiner has referenced Suffin to overcome this deficiency. However, it is respectfully submitted that Suffin, too, fails to teach the aforementioned limitations. Specifically, Suffin is directed only to detecting, extracting and comparing a multivariate QEEG descriptor to a norm value and quantifying a degree of abnormality based on the descriptor value. (*See* Suffin, col. 9, li. 51 – col. 15, li. 67; Chart 1.1 - 1.2; Tables 1 - 3.1). The Suffin disclosure includes no teaching or suggestion to determine a chemical imbalance in CSF based on detected brain activity and further shows no relationship between brain activity and a chemical imbalance in the CSF. The mere

fact that Suffin teaches detection of brain activity is not enough to overcome the fact that neither Suffin nor Reich teaches or suggests a correlation between brain electrical activity and a chemical imbalance in the CSF. It is therefore submitted that the modification proposed by the Examiner constitutes an improper hindsight reconstruction of the invention and is not allowable.

Furthermore, it is respectfully submitted that the proposed combination of Reich and Suffin would change the principle of operation of Reich and is therefore not allowable for this additional reason. Specifically, Reich teaches an infusion and withdrawal of fluids, a flow rate thereof being affected by a pressure sensor and an algorithm that measures the pressure upstream and downstream of a flow restrictor with a known flow resistance to determine if the patient is in an upright or supine position to account for changes in gravity. (*See* Reich, ¶ [0024]- [0025], [0036] - [0037]; Fig. 1). Modifying the Reich device so that the infusion and withdrawal rates are dependent on a “determined chemical imbalance,” as recited in claim 1, would change the principle of operation of the Reich device by obviating the need for the supine and upright withdrawal modes and rather making the delivery and withdrawal of fluids from the patient dependent on brain activity. Reich makes no disclosure of the relevance of “brain activity,” as recited in claim 1 to a standing position and rather, explicitly indicates the importance of a pressure sensor in maintaining a proper CSF turnover rate. (*See* Reich, ¶ [0012] - [0013]). Similarly, Suffin is merely directed to detecting and analyzing a QEEG and also provides no motivation for combination with the device of Reich. Accordingly, modification of the Reich device to affect an infusion or withdrawal of CSF based on a determined chemical imbalance, as indicated in claim 1, would interfere with the function of providing such a function based on a patient’s position and thus, change the principle of operation thereof. It is therefore submitted that the proposed modification is not allowable for at least this additional reason. It is therefore respectfully submitted that claim 1 and its dependent claims 2 - 4, 6, 9, 10, 12 - 19 and 47 - 49 are allowable over Reich and Suffin.

It is therefore respectfully submitted that neither Reich nor Suffin, taken alone or in combination, teach or suggest a method comprising “detecting and analyzing brain activity of a patient”, “determining a chemical imbalance present in the CSF based on the detected and analyzed brain activity,” and “treating the patient based on the determined chemical imbalance by one of supplying an agent to the CSF and withdrawing a quantity of CSF via the second conduit,” as recited in claim 1. It is submitted that claim 1 and its dependent claims 2 - 4, 6, 9,

10, 12 - 19 and 47 - 49 are allowable over Reich and Suffin for at least this reason.

Claim 20 recites limitations substantially similar to claim 1, including a system for treating disorders of the central nervous system (CNS), comprising first and second conduits having distal ends which, when in an operative position, “open into a portion of a patient’s CNS with direct access to cerebrospinal fluid (CSF) and wherein, when in the operative position, a proximal end of the second conduit opens to drain CSF from the CNS and permanently prevent the drained CSF from reentering the CNS” and a first pump coupled to a reservoir holding a first material and “the first conduit for introducing the first material to the CNS via the first conduit” in combination with “*a brain activity detection unit for detecting and analyzing a chemical imbalance present in the CSF based on the brain activity of the patient.*” It is therefore respectfully submitted that claim 20 is allowable over Reich and Suffin for the same reasons noted above with respect to claim 1. Because claims 21, 23, 27, 28, 30 - 35 and 50 - 52 dependent from and therefore include all of the limitations of claim 20, it is respectfully submitted that these claims are also allowable.

Claims 5, 11, 22 and 29 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Reich in view of Suffin in further view of U.S. Patent No. 6,436,091 to Harper et al. (“Harper”). It is respectfully submitted that Harper does not cure the deficiencies noted above with respect to Reich and Suffin and that claims 5, 11, 22 and 29 are therefore allowable for at least the reasons given above in support of the patentability of claims 1 and 20 from which these claims depend.

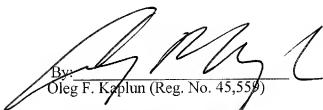
Claims 7, 8, 25 and 26 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Reich in view of Suffin in further view of U.S. Published Appln. No. 2003/0130645 to Brengle et al. (“Brengle”). It is respectfully submitted that Brengle does not cure the deficiencies noted above with respect to Reich and Suffin. It is therefore respectfully submitted that claims 7, 8, 25 and 26 are allowable for at least the reasons given above in support of the patentability of claims 1 and 20.

**CONCLUSION**

In light of the foregoing, Applicant respectfully submits that all of the presently pending claims are in condition for allowance. All issues raised by the Examiner having been addressed, an early and favorable action on the merits is earnestly solicited.

Respectfully submitted,

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By: \_\_\_\_\_  
Oleg F. Kaplun (Reg. No. 45,559)

Fay Kaplun & Marcin, LLP  
150 Broadway, Suite 702  
New York, New York 10038  
Tel: (212) 212-619-6000  
Fax: (212) 619-0276